Republic, [4]Oncologia Medica Addarii Policlinico S.Orsola Malpighi, Bologna, Italy, [5]Son Llatzer, Palma de Mallorca, Spain, [6]Uniwersytecki Szpital Kliniczny, Worklow, Poland, [7]Pierre Fabre, Boulogne Billancourt, France, [8]STAT PROCESS, Paris, France

OBJECTIVES: To assess the burden of illness associated with advanced breast cancer treated with vinorelbine oral (VinO) or IV (VinIV) from the perspective of patients and caregivers in 5 European countries. **METHODS:** This was an observational, prospective, international, multicentric study. Patients were included in the study at the beginning of their 2nd cycle of chemotherapy with vinorelbine and categorized in 2 groups depending on whether they are receiving VinO or VinIV. At baseline (V0) and at the end of the 2nd cycle of chemotherapy (V1), patients and caregivers were asked to complete self-administered questionnaires: SF-12, EORTC-QLQ-C30 (only for patients) and burden of illness. **RESULTS:** At baseline, there were no major differences in demographic and clinical characteristics between the two groups. VinIV was prescribed monotherapy in 56.9% and 62.5% for VinO. Patients receiving VinO were predominantly treated with monotherapy. In addition, as measured with SF-12, patients with VinO (n=128) had, at end of cycle 1 and end of cycle 2, significantly more favourable outcomes in physical summary score, role physical, role emotional and mental health (all p<0.05) than those treated with VinIV (n=51). Trends for a better caregiver mental score and social functioning were also observed with VinO (cycle 1 and 2; p<0.10). From a patient perspective, no major difference was reported on the burden of illness between the two groups, however, a trend for a better "overall impact on daily life" was observed in VinO patients. Major significant differences, showing a lower burden of illness with VinO, were also reported from caregivers (Social functioning, Overall impact on daily life). **CONCLUSIONS:** Oral vinorelbine showed some benefits over the IV form for both patients and caregivers, particularly in health related QoL and burden of illness.

PCN246

QUALITY OF LIFE IN ADULT INTRADURAL PRIMARY SPINAL CORD TUMORS: SHORT FORM–36 CORRELATES WITH THE SCALES OF MCCORMICK AND AMINOFF-LOGUE

Nobre M[1], Guirado V[2]

[1]Heart Institute (InCor) São Paulo University, São Paulo, Brazil, [2]Hospital da Clínicas - São Paulo University, São Paulo, Brazil

OBJECTIVES: Validity and reliability are important characteristics of any instrument. Generic instrument are designed for use in any population; however, their validity and reliability in particular diseases should be verified to ensure their appropriateness. In this study the authors assessed the validity and reliability of the Medical Outcomes Study Short Form–36 (SF-36), a generic instrument, in a population of patients with intradural primary spinal cord tumors (IST). **METHODS:** The SF-36 was administered to a cohort of patients with IST on an outpatient basis. Symptom-related data derived from a structured interview and physical examination findings were used to classify cases according to the scales of McCormick and Aminoff-Logue. Construct validity was assessed by determining whether SF-36 scores correlates with the spinal cord tumors scores (McCormick score and Aminoff-Logue score) by using the Cuzick nonparametric test for trend. The reliability of the SF-36 scores was assessed using Cronbach alpha. **RESULTS:** One hundred patients with IST completed the SF-36. Construct validity was demonstrated by confirming the hypothesized relationship between SF-36 scales and the scales of McCormick (p _ 0.003), Aminoff-Logue deambulation subscale (p _ 0.025), Aminoff-Logue micturition subscale (p _ 0.013), and the Aminoff-Logue defaecation subscale (p _ 0.004). Reliability was demonstrated for all eight SF-36 domain scales and the physical component and mental component summary scales, in which Cronbach alpha satisfied the Nunnally criterion of >0.85. **CONCLUSIONS:** The SF-36 provides valid and reliable data on patients with IST.

PCN247

PREDICTORS OF UTILITY OVER TIME AMONG PATIENTS WITH TREATMENT-NAÏVE ADVANCED MELANOMA FROM THE PHASE 3 CHECKMATE 066 TRIAL

Paly V[1], Colby C[2], Gilloteau I[3], Exuzides A[4], Briggs A[5]

[1]ICON Plc, Morristown, NJ, USA, [2]ICON plc, San Francisco, CA, USA, [3]Bristol-Myers Squibb, Princeton, NJ, USA, [4]ICON, plc., San Francisco, CA, USA, [5]Institute of Health and Wellbeing, University of Glasgow, Glasgow, UK

OBJECTIVES: The aim of this analysis was to assess predictors of health-related quality of life over time, and to estimate utilities for patients with treatment-naïve advanced melanoma in the randomized CheckMate 066 trial comparing nivolumab with dacarbazine for use in a cost-effectiveness model (CEM). **METHODS:** The EQ-5D was administered at baseline and every 6 weeks in CheckMate 066 and was used to generate index utility scores using the UK time trade-off (TTO) method. Covariates were based on a combination of prior analyses from large trial datasets, including patient demographic and clinical characteristics, quantitative metrics of fit, qualitative/clinical plausibility, and relevance to the CEM. Several longitudinal mixed linear models were explored using different covariate sets. **RESULTS:** This analysis included 288 patients and 1,125 visits where the EQ-5D was administered. Mean baseline utility score was 0.75 for nivolumab, 0.69 for dacarbazine, and 0.72 across both treatment arms. The final model included baseline utility (to adjust for imbalance between treatment arms), progression status (pre/post), days until death or end of follow-up (<30 days/30+ days), and treatment arm. Parameter estimates in the model were 0.603 for baseline utility (P<0.001), –0.074 for progression status (P<0.001), –0.022 for <30 days left (P=0.092), and –0.069 for treatment arm (dacarbazine vs nivolumab; P=0.008). When implemented in the CEM, the utility estimate for the pre- and post-progression states were 0.802 and 0.728, respectively (applying nivolumab as the treatment arm). A decrement for the month preceding death was applied using the estimate for <30 days until death or end of follow-up (–0.022). **CONCLUSIONS:** These results showed that baseline utility, progression, <30 days until death or end of follow-up, and treatment arm are all predictors of utility over time, which is consistent with prior work in melanoma. As data mature, these analyses will be replicated in this and other nivolumab trials.

PCN248

COST-UTILITY ANALYSIS OF ENZALUTAMIDE FOR PATIENTS WITH CHEMOTHERAPY-NAÏVE METASTATIC CASTRATION-RESISTANT PROSTATE CANCER (MCRPC) AFTER FAILURE OF ANDROGEN DEPRIVATION THERAPY (ADT)

Vicente C[1], Loblaw A[2], North S[3], Kassouf W[4], Naidoo S[5], Husein F[6], Nakhaipour HR[6]

[1]PIVINA Consulting Inc., Mississauga, ON, Canada, [2]University of Toronto, Toronto, ON, Canada, [3]University of Alberta, Edmonton, AB, Canada, [4]McGill University Health Centre, Montreal, QC, Canada, [5]Astellas, Chertsey, UK, [6]Astellas, Markham, ON, Canada

OBJECTIVES: Enzalutamide prolonged overall survival and radiographic progression-free survival (rPFS), delayed initiation of cytotoxic chemotherapy and maintained quality of life in patients with chemotherapy-naïve mCRPC after failure of ADT (PREVAIL; Beer et al 2014). The cost-effectiveness of enzalutamide, compared with abiraterone plus prednisone (ABI+P) for patients with chemotherapy-naïve mCRPC, was evaluated from the perspective of the Canadian Ministries of Health (MoH). **METHODS:** A Markov model was developed to capture time spent by patients in various health states: stable, progression and death. Results were reported as incremental costs per additional quality-adjusted life year (QALY) gained over a 10-year period. Transition probabilities were derived from patient-level data from PREVAIL and a network meta-analysis (NMA) of available trials. Base case analysis focused on direct medical costs from the Canadian MoH perspective. Cost data was obtained from a variety of Canadian sources, valued in 2015 Canadian dollars. A 5% discount rate was applied to costs and outcomes. Multiple sensitivity analyses were performed. **RESULTS:** NMA results suggested no difference between enzalutamide and ABI+P for overall survival, but indicated that enzalutamide is superior to ABI+P for rPFS (hazard ratio 0.35; credible interval 0.27, 046). The improvement in rPFS translated into a longer mean duration of stable disease with enzalutamide (36.7 months) than with ABI+P (16.4 months), and greater total QALYs (enzalutamide 2.65; ABI+P 2.23). From the Canadian MoH perspective, enzalutamide had an incremental cost-effectiveness ratio (ICER) of $92,690 per additional QALY gained versus ABI+P. The ICER was robust over a wide range of sensitivity analyses. In the probabilistic sensitivity analysis, the mean ICER was $110,036 per QALY gained versus ABI+P, with >60% of iterations falling below a willingness-to-pay threshold of $100,000 per QALY gained. **CONCLUSIONS:** Enzalutamide is considered a cost-effective treatment option compared to ABI+P in patients with chemotherapy-naïve mCRPC after failure of ADT.

PCN249

EASTERN COOPERATIVE ONCOLOGY GROUP (ECOG) PERFORMANCE STATUS (PS) IS AN INDEPENDENT PREDICTOR OF HRQOL IN UNRESECTABLE OR METASTATIC MELANOMA

Harrison JP, Kim H

Bristol-Myers Squibb Australia, Mulgrave, Australia

OBJECTIVES: In analysis of health state utilities derived from a nivolumab phase III clinical trial a statistically significant difference in baseline utilities was noted between nivolumab (NIVO) and dacarbazine (DTIC) treatment arms. The aim of this study was to analyse and assess possible drivers of this difference in mean baseline utility. **METHODS:** Patient demographics and baseline disease characteristics were compared between treatment arms to identify any variables which may be responsible for the observed differences in baseline utilities. All identified variables were included in a generalised linear model and tested for significance differences in a stepwise manner to determine the final predictive utility model. **RESULTS:** Population demographics and baseline disease characteristics were generally well balanced between treatment arms, however patients randomised to NIVO were generally of better ECOG performance status (70.5% and 28.6% for PS 0 and 1 respectively) than those randomised to DTIC (58.2% and 40.4%). A generalised linear regression model of utility therefore included ECOG performance status in addition standard variables age, sex, weight, smoking history and metastatic stage. After stepwise elimination of non-significant variables, ECOG performance status was found to be a strongly significant predictor of health state utility (p<0.000) as was sex (p<0.000) and age (p=0.006). Whilst metastatic stage remained in the final model specification as these were pre-defined stratification factors, neither was a significant predictor of health state utility (p=0.724, p=0.493 respectively). **CONCLUSIONS:** ECOG performance status was found to be an independent predictor of health state utility in addition to age and sex. As such it is critical that any economic evaluation of an intervention in this patient population identifies any differences in performance status between intervention and comparator arms and seeks to establish the impact any difference may have on subsequent results.

PCN250

HEALTH-RELATED QUALITY OF LIFE IN BLADDER CANCER: A SYSTEMATIC LITERATURE REVIEW

Bartley K[1], DeBusk K[1], Duff S[2]

[1]Genentech, South San Francisco, CA, USA, [2]Veritas Health Economics Consulting, Inc, Carlsbad, CA, USA

OBJECTIVES: Bladder cancer (BC) is a disease with a high recurrence rate, necessitating invasive, repeated treatments that can meaningfully impact patient health-related quality of life (HRQoL). The goal of this review was to summarize the BC HRQoL literature in order to assess the impact of BC by stage and treatment. **METHODS:** A systematic literature search of studies indexed in PubMed was conducted without language or publication year limitations. Due to the large volume of literature, subsequent review was refined to studies published since 2005, excluding reports utilizing single-use HRQoL measures without evidence of validation. **RESULTS:** A review of ~1,700 abstracts yielded a final set of 62 peer-reviewed articles (published 2005 – 2014). Eleven HRQoL measures (8 disease-specific, 3 generic) were identified (EORTC QLQ-C30 and SF-36 most commonly used, in 25 and 21 studies, respectively). BC-specific modules such as the EORTC QLQ-NMIBC24 were included less frequently, with no BC-specific module in more than 8 studies. The majority of studies were of retrospective, cross-sectional study design. HRQoL impact of radical cystectomy for muscle